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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,764	09/27/2000	Joseph R. Pisegna	M-8978 US	7433

22798 7590 06/28/2002

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 06/28/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/671,764

Applicant(s)

PISEGNA ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ . 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U. S. C. 121:

I. Claims 1-12, 20-29 and 31, drawn to a method for increasing the efficacy of a gastric proton pump inhibitor in a mammal by administering a pentagastrin, gastrin or analog in conjunction with a proton pump inhibitor, and to a kit for treating excess gastric acid secretion comprising a container containing a proton pump inhibitor and a container containing a pentagastrin, gastrin or analog, classified in class 514, subclasses 17 and 18, and class 546, subclasses 273.7.

II. Claims 13-19 and 30, drawn to a method of increasing urinary sodium excretion and urine volume by administering a cholecystokinin (CCK) receptor agonist such as pentagastrin, and to a kit for increasing urinary sodium excretion in a mammal comprising a container containing a pentagastrin, gastrin or analog, and instructional materials describing the use of a pentagastrin, gastrin or analog, classified in class 514, subclasses 17 and 18.

Should Group II be elected, applicant is required to select one pathological condition cited in claim 16. Each pathological condition, absent factual data to the contrary, is a distinct disease. This is not a species election, rather each disease is held as patentably distinct.

2. The inventions are distinct, each from the other because of the following reasons:

The method of Invention I is distinct from the method of Invention II because the method steps, the agent used and outcomes are wholly different between two inventions, e.g., Invention I is to increase the efficacy of a gastric proton pump inhibitor using a pentagastrin, gastrin or

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analog along with a gastric proton pump inhibitor, while Invention II is to increase urinary sodium excretion and urine volume using a pentagastrin, gastrin or analog.

The method of Invention I is distinct from the product of Invention II because the product of Invention II can be neither made by nor used in the method of Invention I, e.g., Invention I is a method of increasing the efficacy of a gastric proton pump inhibitor using a pentagastrin with a gastric proton pump inhibitor, while the product of Invention II is a kit for increasing urinary sodium excretion comprising a pentagastrin, gastrin or analog, and instructional materials describing the use of a pentagastrin, gastrin or analog.

The product of Invention I is distinct from the product of Invention II because the two groups of products are physically and functionally distinct entities, e.g., Invention I is a kit for treating excess gastric acid secretion comprising a proton pump inhibitor and a pentagastrin, gastrin or analog, while Invention II is a kit for increasing urinary sodium excretion comprising a pentagastrin, gastrin or analog, and instructional materials describing the use of a pentagastrin, gastrin or analog.

The method of Invention II is distinct from the product of Invention I because the product of Invention I can be neither made by nor used in the method of Invention II, e.g., Invention II is a method of increasing urinary sodium excretion and urine volume using a pentagastrin, respectively, while Invention I is a kit for treating excess gastric acid secretion comprising a proton pump inhibitor and a pentagastrin, gastrin or analog.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, and because Inventions I-II require different searches but are not co-extensive,

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examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

Karen Cochrane Carlson PhD
KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER

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June 25, 2002